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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,208	01/22/2004	Masatoshi Narahara	HIRA.0136	3740

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EXAMINER

CROW, ROBERT THOMAS

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/761,208	Applicant(s) NARAHARA ET AL.	
	Examiner Robert T. Crow	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/942,563.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The Information Disclosure Statements filed 22 January 2004 and 9 June 2004 is acknowledged. However, only the Abstracts of Documents 11-187900 (Japan) and 2000-063154 (Japan) are being considered because English translations of the remainder of the documents have not been provided.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 9 January 2001. However, no English language translation has been provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-3 are indefinite in claim 1, which recites the limitation "a method for manufacturing an array" in line 1 of the claim, because the method steps do not result in an "array." Claims 1-3 are also indefinite in claim 1, which recites the limitation "the second region" in line 7 of claim 1. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the word "the" be replaced with "a."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Chrisey et al (U.S. Patent No. 5,688,642, issued 18 November 1997).

Regarding claim 1, Chrisey et al teach a method of manufacturing a nucleic acid array for detecting nucleic acids by hybridization comprising: providing a substrate in which maleimide groups are formed on a surface (column 3, lines 39-57, column 7, line

65-column 8, line 13, and Figures 1 and 3); immobilizing single-stranded nucleic acid probes for hybridizing to the nucleic acids on a first region of the surface covalently (e.g., nucleic acid molecules [NAMS] are attached to a heterobifunctional crosslinker after a substrate is irradiated to create active regions; column 6, lines 33-44 and Figures 1 and 3); after said immobilizing single-stranded nucleic acid probes, hydrolyzing maleimide groups formed on the second region where said single-stranded nucleic acid probes are not immobilized (e.g., blocking agents are used to prevent absorption of other molecules to the substrate; column 7, lines 15-20).

Regarding claim 2, Chrisey et al teach the method of claim 1, wherein said single stranded probes are bonded via thioether linkage to said maleimide groups (e.g., Example 9 and Figure 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under

37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chrisey et al (U.S. Patent No. 5,688,642, issued 18 November 1997) in view of Okinaka et al (U.S. Patent No. 5,155,190, issued 13 October 1992).

Regarding claim 3, Chrisey et al teach a method of manufacturing a nucleic acid array for detecting nucleic acids by hybridization of claim 1, the method comprising: providing a substrate in which maleimide groups are formed on a surface (column 3, lines 39-57, column 7, line 65-column 8, line 13, and Figures 1 and 3); immobilizing single-stranded nucleic acid probes for hybridizing to the nucleic acids on a first region of the surface covalently (e.g., nucleic acid molecules [NAMS] are attached to a heterobifunctional crosslinker after a substrate is irradiated to create active regions; column 6, lines 33-44 and Figures 1 and 3); after said immobilizing single-stranded nucleic acid probes, hydrolyzing maleimide groups formed on the second region where said single-stranded nucleic acid probes are not immobilized (e.g., blocking agents are used to prevent absorption of other molecules to the substrate; column 7, lines 15-20). Chrisey et al are silent with respect to alkaline solution.

However, Okinaka et al teach the hydrolysis of maleimide at alkaline pH with the added advantage that they hydrolysis takes place very rapidly (column 6, lines 16-20).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method as taught by Chrisey et al with the alkaline solution of Okinaka et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in rapid hydrolysis as explicitly taught by Okinaka et al (column 6, lines 16-20).

3. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koster et al (U.S. Patent No. 6,133,436, issued 17 October 2000) in view of Siiman et al (U.S. Patent No. 5,945,293, issued 31 August 1998).

Regarding claim 1, Koster et al teach a method of manufacturing a nucleic acid array comprising : providing a substrate (e.g., beads linked to a solid support; Abstract) in which maleimide groups are formed on a surface (e.g., 4-(N)-maleimidomethyl)cyclohexane-1-carboxylate [SMCC] is used as a crosslinking agent on the surface of the bead; column 5, lines 5-20); immobilizing single stranded nucleic acid probes for hybridizing to the nucleic acids on a first region of the surface covalently (Abstract). Koster et al are silent to hydrolyzing the maleimide groups.

However, Siiman et al teach the use of beads for immobilizing biological molecules having pendant maleimidyl groups for conjugation to thiol containing groups (e.g., coated particles for immobilizing biological molecules with sulfhydryl groups; column 22, lines 59-65) wherein maleimide groups are hydrolyzed after conjugation (e.g., unreacted maleimidyl groups are blocked in PBS buffer [column 23, lines 49-53], wherein PBS buffer is defined as an aqueous solution having a basic pH [e.g., 7.2]; column 16, lines 23-27), with the added advantage of resulting in the blocking of unreacted functional groups (column 10, lines 61-63).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method as taught by Koster et al with the hydrolysis of Siiman et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in the blocking of unreacted functional groups as explicitly taught by Siiman et al (column 10, lines 61-63).

Conclusion

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-

1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert T. Crow
Examiner
Art Unit 1634


5/17/06


BJ FORMAN, PH.D.
PRIMARY EXAMINER